MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
1300 13th Street, N.W.
Washington, D.C.

Thursday, September 11, 2003
10:20 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
SHEILA P. BURKE
AUTRY O.V. "PETE" DeBUSK
NANCY-ANN DePARLE
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CAROL RAPHAEL
ALICE ROSENBLATT
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DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.
NICHOLAS J. WOLTER, M.D.

AGENDA ITEM:

Outpatient dialysis payment issues
-- Nancy Ray

MR. HACKBARTH: Okay, let's begin the afternoon session. The first issue for this afternoon is the agenda for outpatient dialysis. Nancy, begin whenever you're ready.

MS. RAY: Good afternoon. I'm here to talk to you about two outpatient payment issues, the first one being MedPAC's workplan to assess payment adequacy, and the second one being our comment on the Secretary's report to broaden the outpatient dialysis payment bundle. My presentation is reverse of your mailing materials, just to confuse you.

As you recall how Medicare pays for outpatient dialysis services prospectively, it's called the composite rate, for each dialysis treatment. Then facilities receive separate payment for certain injectable drugs. The payment rate for erythropoietin, as Chantal mentioned, is $10 per 1,000 units and that is set by the Congress, that payment rate. The other covered drugs that facilities can separately bill for, like vitamin D analogs and injectable iron and antibiotics, Medicare pays providers 95 percent of the average wholesale price.

Just some outpatient dialysis data that we calculated. This represents 2001 estimated spending for freestanding dialysis facilities. That was $3.3 billion in 2001. For injectable drugs that was approximately $2.3 billion. To give you a flavor for how these have increased over time spending, between 1996 and 2001 dialysis spending increased by about 6 percent per year. For injectable drugs that increased between '96 and 2001 by about 16 percent per year.

There are a total of 282,000 dialysis patients in 2001 and they were treated at roughly 3,900 facilities. Approximately 80 percent of those facilities are freestanding.

Set forth in your mailing materials was a proposed workplan for updating payments for outpatient dialysis services for calendar year 2005. This will be published in our March 2004 report. As you recall, we each year make a recommendation about the payment level, the payment update for the composite rate. We will follow our update framework to assess payment adequacy, in the first step, by estimating payments and cost and assessing market conditions. Then the second step we will account for providers' cost changes in the next payment year.

I want to highlight at this point three new analyses that we propose doing. These were set forth in your workplan. I'd be happy at the conclusion of the presentation to take any other questions you may have about the workplan.

The first new analysis is an outgrowth of our June 2003 analysis that looked at and compared quality of care to providers' costs. Here we want to take this data and we

want to compare payments and costs for those high-quality, low-cost providers to those of other providers as a part of our payment adequacy analysis.

The second new analysis we would like to do is to evaluate CMS's recently developed market basket index for composite rate services. As I will be presenting, in the Secretary's report is a market basket index for services that the current composite rate includes. So we would like to compare how well this market basket index predicts providers' costs over time versus the MedPAC/ProPAC one which we have used now since the early '90s.

The final new analysis I'd like to talk about is we'd like to more closely examine the relationship between providers' costs and patient case mix. We touched upon this in our June 2003 report and we would like to extend it a little bit more. We think this is important as a broader bundle is considered by CMS for new information to come to light about the relationship between cost and patient case mix.

So with that in mind I'd like to switch MedPAC's comment on the Secretary's report. A draft comment letter report was included in your mailing materials. Just to give you some background, BIPA required the Secretary to develop a system which includes in the composite rate drugs and laboratory tests that are routinely furnished during dialysis which are currently separately billable facilities. BIPA also required the Secretary to develop the dialysis market basket index which can be used to update the composite rate bundle.

In response to BIPA, CMS submitted a report to the Congress in May which sets forth the issues that the agency will look at as they proceed with designing and implementing the expanded PPS. So the report that does not set forth a broader payment system. It sets forth the issues that the Secretary will consider as he designs and modernizes the dialysis payment system.

As a next step, the agency is contracting with the University of Michigan to develop payment options and specific recommendations for a bundled approach. Just to let you know, the contractor has put together a technical advisory committee. MedPAC is a member of this committee and the first meeting will be in Chicago in November.

As you recall, the BIPA study was prompted by the Commission's concerns about how Medicare pays for outpatient dialysis services. In in March 2000 report we concluded that the payment system did not pay appropriately for outpatient dialysis services because neither payment for services in the bundle nor payment payments for certain services outside the bundle accurately reflected facilities' expected costs. In our March 2001 report we made four recommendations for modernizing the payment system. That was for expanding the bundle, reevaluating the unit of payment, adjusting for factors affecting providers' costs, and refining the wage index.

The draft comment letter report in your mailing materials raises six issues that the Secretary should

consider as he modernizes this payment system. These six issues are expanding the payment bundle, refining the unit of payment, adjusting for factors affecting providers' cost, setting the base payment rate, updating, and monitoring for quality. I'd like to briefly take you through each of these six issues.

The first issue is expanding the payment bundle. In 2001 we recommended including widely-used services like injectable drugs currently excluded from it. CMS in its report also believes that all outpatient services that are related to maintenance dialysis are candidates for inclusion in a bundled PPS, in a broader bundle, regardless of whether those services are provided by the dialysis facility, the lab, or any other supplier.

Our letter raises the issue of potentially including other needed services and also, commonly used services, by dialysis patients. We include three examples, the first one being vascular access services. The 90 percent of all dialysis patients who are on hemodialysis need these services. Vascular access complications are a leading cause of hospitalization. Currently the agency does not permit facilities to bill separately for noninvasive monitoring.

So what we're talking about here is including in the broader payment bundle the noninvasive monitoring of vascular access sites.

CMS's new ESRD disease management demo, one of the options is a broader bundle that includes vascular access care. It's one of the quality indicators that the agency is using.

The second service that we raise in the letter potentially to include in the bundle would be nutritional supplements. Malnutrition is a frequent complication of ESRD, and including medical interventions used to prevent or treat malnutrition in the bundle may improve patients' outcomes. CMS's clinical performance measures that they've been publishing since 1993 show that a fair number of dialysis patients do suffer from malnutrition and that this measure has not improved between 1993 and 2001.

The National Kidney Foundation has a clinical guideline on nutrition care. Nutritional supplements were furnished to patients participating in CMS's first ESRD demo, and they de facto have to be provided in the second demo because, again, that's one of the quality measures that providers will be held accountable to.

I would like to point out here that CMS may need to revisit its current coverage policy on nutritional supplements because it is restrictive right now.

The third service we also highlight in the letter is including Medicare covered preventive services. The more than half of all ESRD patients who have diabetes are less likely to receive diabetic preventive services, such as lipid and glycemic control testing than the general Medicare population. Including these and other preventive services may increase their overall use, minimize the extent of geographic variation, in long term improve patients'

outcomes.

I'd like to raise two important issues related to broadening the bundle. First, broadening the bundle -- and we point this out in the letter -- broadening the bundle for both injectable drugs and other related services, and other needed services, must be coupled with quality monitoring to hold providers accountable.

Second, additional analysis will need to be done to determine whether broadening the bundle requires new money. I think this is an open question. At issue is whether the current pool of dollars, that is the dialysis and injectable drug dollars, is sufficient. What we know right now is that Medicare's payment per injectable drug significantly exceeds providers' costs and that there is wide variation in the use of these injectable drugs based on data from the U.S. renal data system.

Moving on to the second issue is refining the unit of payment. Currently, the composite rate's unit of payment is a single dialysis session. Here I make the same point that we made back in our March 2001 report, and that is, changing the unit of payment to either a week or a month might give providers more flexibility in furnishing care and better enable Medicare to include in the broader bundle services that are not always furnished during each session.

The third issue is concerned setting the base payment rate and using cost report data. Here I'd like to make to issues, the first one concerning the use of cost report data from hospital-based facilities. Like I said previously, about 20 percent of all facilities are hospital-based. Their cost may be affected by the cost allocation decisions made by hospitals. As you recall, when the CMS set the initial payment rate in 1981 they found that hospital-based facilities incurred higher costs but they attributed that to overhead rather than to patient case mix or complexity.

The second issue concerning setting the base payment rate is the importance of using audited cost report data.

Moving on then, in our letter we talk about the need to adjust the base payment rate for factors affecting providers' costs. These factors include dose, frequency, case mix, and modality. As you recall, the composite rate is only adjusted using two very dated wage indices. I'd just like to briefly take you through these factors.

For dose and frequency, our letter points to the need to collect this information from a representative sample of providers because these data will not be available in providers' cost reports.

For case mix, our June 2000 analysis and other published literature -- our June 2000 analysis showed that the aggregate cost for composite rate services and injectable drugs varies widely, suggesting that some of the difference in facilities' costs may be explained by the health status of its patients. Again, this is an issue that in our workplan we'd like to look at in greater detail.

Now generally Medicare's -- the composite rate

does not vary based on dialysis method. MedPAC's recent analysis of 2000 cost report data shows that providers' costs do vary. The 2000 data show that there's a 10 percent difference, that the cost of providing in-center hemodialysis is 10 percent greater than the cost of peritoneal dialysis. We will be updating that to the 2001 number. There was a technical difficulty in CMS's data.

Medicare makes one exception with payment based on modality. This is an issue that neither the Secretary's report nor our 2001 analysis explicitly considered. Medicare has a higher payment rate for one form of peritoneal dialysis -- it's called continuing cycling peritoneal dialysis -- when patients obtain their care from dialysis suppliers, from suppliers instead of from a dialysis facility. The payment rate is 30 percent greater when CCPD is provided under method II from suppliers than under the composite rate payment, method I.

There is no evidence to suggest that the cost incurred by suppliers for furnishing CCPD are any different than the costs incurred by facilities. If suppliers incur higher costs for furnishing this modality to a more severely ill patient population, then adjusting payment to account for case mix will appropriately ensure that payments match their costs.

As I point out in your mailing materials, the OIG recently published a report on home dialysis payment method and they found that the higher CCPD payment limites may be driving patterns of care in that there's an increasing trend of patients selecting method II payment between 1997 and 2001. They also point out that the program is burdensome to administer and requires additional program oversight. They calculated that Medicare had paid an extra $15.3 million and beneficiaries paid an additional $3.1 million in copays under method II than method I.

The OIG recommended that CMS limit their method II payments to the composite rates. In response to the report, CMS stated that their interpretation of the statute is that it intends that the payment limits for CCPD should be set higher, at a higher level than under the composite rate. So at the conclusion of my presentation I will be presenting a draft recommendation for your consideration.

I already talked about setting the base payment rate so let's move on to updating the broader payment bundle. So the issue here is that when we modernize the payment system, broadening of bundle and adjusting for factors known to affect providers' costs, the point we make here is we will need to take the bundled payment and update it over time to account for changes in the costs of services and how they are delivered.

The final issue that we raise is monitoring quality. To ensure quality we will need to hold providers accountable for all of the services that they provide in the broader bundle. CMS will need to develop new measures like for lab tests and for certain injectable drugs like antibiotics. The agency will also need to set up the information systems necessary to collect timely data, and

that they should continue their public reporting of data as they have done since 1993.

Now moving on to the second issue covered in the Secretary's report, again, BIPA mandated that they develop a market basket index, a dialysis market basket index but for the current composite rate payment bundle. Here we have one principal issue, and that is that the report did not mention how frequently the base weights will be updated. For example, in the inpatient hospital PPS, the base weights are updated every five years.

So moving back to the one exception and the higher payment rate for CCPD, this draft recommendation reads that the Congress should give the Secretary the discretion to modify the home dialysis payment rate for suppliers, the method II rate, so that payment can better reflect the cost of efficient suppliers.

We think that this recommendation is consistent with the Commission's position that payment reflect the cost of efficient providers as well as that payment for services furnished in different settings should not create financial incentives that inappropriately affect decisions about where care is provided.

That concludes my formal presentation.

MR. HACKBARTH: What I'd like to do is come back to the recommendation after we've had our discussion. Could I begin the discussion by asking you, Nancy, to help me think through some of the issues around broadening the bundle? We've said that we would like to see the bundle broadened to include some services that we think may be overused or provided at a cost higher than is necessary. Then there are services where we think they may be underused, vascular access and preventive services, and the like.

Now ordinarily I would think that when you put services in a bundle, what you're doing is creating an incentive to economize and potentially reduce the provision of services. If we've got services like vascular access where we think they're currently underprovided, putting them into the bundle -- I don't know, is maybe a little counterintuitive for me.

Now I did hear your very important qualification that we would like to monitor the actual provision of those services. But for me, that begs the question, what happens when you find that a particular provider is underproviding those services and they're now in the payment bundle? You've paid up front for them. What is the response to underprovision of these desirable services? In a fee-for-service system, if they don't provide them, they just don't get paid, so there's an immediate, automatic response to not providing the desired services. But I'm not sure I see how it would work in a bundled payment. Did that come out clearly?

MS. RAY: Yes, it did. First of all, going back to our March 2001 report, the thought there was that these injectable drugs are provided some during each dialysis treatment. They're commonly used and that, yes, there was

the higher payment. It would provide providers with a better incentive to furnish them as efficiently as possible, and for that reason to include it in the bundle.

That reasoning behind the vascular access is that patients are going into the facility three times a week. That the monitoring for that service can easily be done by the provider. My sense from providers is that this would be done perhaps once a quarter, although that's something that we could follow upon.

So your question, I think you raise a very good question then, both with respect to vascular access monitoring as well as the other services included in the broader bundle. What does the agency do if providers -- if a provider is not furnishing that service? There needs to be some mechanism to hold facilities accountable for. It could be quality-based payment. It could be taking more drastic action.

MR. HACKBARTH: I assume in each case we would be talking about a rate so it's a continuous variable as opposed to they're provided or not. Some might be doing it 99.9 percent of the time, and another 94 percent of the time, and some 64 percent of the time. What are the consequences that attach to different levels of performance?

DR. REISCHAUER: In a sense it would have to be risk or case adjusted, and it would have to be facility by facility to impose an effective mechanism.

Do I have the floor besides commenting on your comment?

MR. HACKBARTH: I saw some other hands. If there were other comments on the issue that I've raised -- otherwise, Bob. Joe, did you have a comment on this?

DR. NEWHOUSE: I was just going to say that, as I understand historical experience, it underscores that because the basis for Epo payment, if I remember right, Nancy, was $40 for 10,000 units from '89 to '91, and there was thinking, although I'm not sure there was any real evidence, that it was being underprovided, so the basis was changed to per 1,000 units; is that right?

MS. RAY: That's right. We raise that in the letter report. The way CMS originally paid for Epo was a lower payment rate. I forget the exact --

DR. NEWHOUSE: It was a larger unit.

MS. RAY: A larger unit. So what was happening -- and there was very good evidence that what was happening was that providers were underdosing patients. Because of that, the payment rate was changed to the actually $11 per 1,000 units.

DR. NEWHOUSE: Now the problem with going to a separate fee here is that, in effect this is the whole problem of trying to set a price for a drug where you have very low marginal costs and the drug is developed and we're into the drug price control business.

DR. MILLER: Nancy, particularly on things like the vascular access and nutrition, the stuff that we're talking adding to the bundle, after you put the two, the

drugs and the current bundle together, isn't it true -- I'm thinking in conversations I've had with you, there's very clear quality indicators associated with those things, are there not?

MS. RAY: Yes, there are. So it's just a matter of going back to Glenn's point, monitoring on a facility by facility basis. That's something that both the CMS and in the partnership the ESRD networks can collect on, monitoring it and having some sort of mechanism to ensure that providers are improving themselves.

DR. REISCHAUER: I should know this but remind me, what fraction of dialysis patients are paid for by private insurers like Jack? I mean, 10 percent, 40 percent?

MS. RAY: I would say roughly -- the Medicare secondary period right now is for 30 months. I would say probably roughly 20 percent. But I can get a better figure --

DR. REISCHAUER: If it was a large fraction I was going to then say, how do pay for this? Do they do a bundled package? Does it include all of these things, or doesn't it? What do they do to monitor quality? That would be question one.

Question two is, I was wondering is there any reason to provide this service in a hospital? We're talking about the differential payment between hospitals and facilities and for ambulatory surgical centers you can make some arguments on why certain people with more severe instances -- I'm saying is there a reason -- we're trying to figure out whether we should pay the hospital more or the same. In other areas we've said our policy is the same. I'm just wondering whether for particularly frail individuals or for particularly severe cases there's a reason why it's good to have it done in an outpatient department of a hospital because of the other services that might be available if something goes wrong or something like that.

MS. RAY: Right. I would answer that generally not. The one exception could be perhaps children. I think children are more likely to be treated in hospital-based facilities. A very, very small fraction of the dialysis population patients are kids. Recall that our numbers as well as others show the real decline in the number of hospital-based facilities. Our numbers track it back to 1993. At the same time, CMS's measures for dialysis adequacy and hematocrit have improved since then.

MS. BURKE: I just had a question going back to our discussion about disease management, and the whole conversation about to what extent we want to encourage that, and in what instances and certain high-risk populations. One of the populations that is often noted are in fact ESRD patients, many of whom have comorbidities. The question really is in discussing this issue, that is how we structure a payment, whether there ought to be any consideration given, or reflection on that conversation as well? I mean, whether we could ever imagine that as we move in this direction for certain population groups whether it would

become part of this or whether we would assume it would be outside of the traditional ESRD provider system.

But it would seem to me, having had that conversation that we ought to at least the question or at least think about it, because the things we look at here -- and it's a terrific paper and I thought the letter actually was quite well done. But there is this separate question over the long-term about whether or not we ought to look at the broader context of how we manage these patients and whether we ought to look at this in isolation of that.

MS. RAY: I think that's an issue that we could definitely raise in the comment letter. I think that's a good point.

DR. ROWE: As far as the patients that commercial payers cover, I think it would be really interesting -- I don't know that we have the data, because we have our data and Medicare has its data, but nobody has both -- to do some sort of a tracking of patients as they progress from commercial payments to Medicare, the same patients with different payment strategies, to see how the frequency of dialysis, the amounts of medications, et cetera, changes. I think that would be very interesting.

And then to see how the dependent variables that we measure as a proxy for quality, such as albumen levels or whatever, change. Of course, patients are getting older and they may have comorbidities that are advancing during this time and all that so you'd have to take that into account. I don't know if that's been done. It may have and I may have missed it, but I think it would be a very interesting analysis.

MR. HACKBARTH: Jack, do you want to address Bob's question about how private payers typically pay for these services, give us a sketch of that?

DR. ROWE: I'm avoiding addressing it because I don't know the answer specifically. We have contracts with a very large number of dialysis providers, and I believe that we pay rates that are negotiated regionally, as opposed to Medicare which is nationally. The network that we have has different providers in different regions, depending on the rates that are negotiated. I believe we pay on the per-dialysis basis. But I don't have all the details of the bundles and stuff. Alice may know for her company. I also think this changes over time, back and forth. But I can certainly get that information.

A couple other questions and comments. Is there still new entry into the marketplace?

MS. RAY: New entry meaning?

DR. ROWE: Dialysis providers.

MS. RAY: You mean like chains? There's four major chains and you can see that over time since I've been tracking that those four chains account for a greater proportion of facilities.

DR. ROWE: I guess it's the number of stations or beds or whatever.

MS. RAY: The number of dialysis stations is increasing and I will be presenting at the December meeting

updated information on that, yes.

DR. ROWE: Because one of the variables that we always used in the past when we were trying to decide whether or not there should be changes in the payments was whether there was continued new entry into the marketplace. So the answer is, it appears that there is continued new entry into the marketplace.

MR. HACKBARTH: And consolidation of existing. So these chains are becoming larger and acquiring other existing facilities as well. So they're expanding their investment in the industry.

DR. REISCHAUER: But the real issue is the number of stations per patient.

DR. ROWE: Right, because the number of patients may be increasing.

DR. REISCHAUER: The number of patients may be increasing and the standard number of times per week may be increasing or decreasing. There's a whole lot of things going on here that would be very hard to --

DR. ROWE: But those are two different questions. It seems to me the number of stations per patient, or 100 patients of whatever it is, who are Medicare beneficiaries or who need dialysis, is a measure of access. Whereas, whether or not the marketplace is seeing new stations at all or a contraction of stations may be more a measure of adequacy of payment. It might be two different things.

MS. RAY: Right.

DR. ROWE: Because if somebody is deciding whether to open a new unit or to add some more stations, they don't really care how many Medicare beneficiaries there are. They care whether or not the use of that station is getting paid in such a way that it's profitable for them.

DR. REISCHAUER: But you'd also want to look at hours, and maybe they're going Saturdays and Sundays or nights. It gets very complicated.

DR. ROWE: I agree. Let me just go on. I've got a couple other little things.

The demonstration project that's been discussed, the new demonstration project in dialysis, fee-for-service, et cetera, should that be discussed or referred to in some way in this letter more than it is? Or is it relevant to some of these questions that are being asked or considered?

MS. RAY: I can highlight it more if you think so. I do raise it when we talk about including vascular access services in the bundle as follows nutritional supplements. Again, in that demo they're going to be using this quality-based incentive payment. We could raise that.

DR. ROWE: I think it would be helpful. It's imbedded deep in this and I think it addressing some of the questions.

A very small point. On page two you make a comment that CMS data show that hemodialysis patients more frequently received intravenous iron, and peritoneal oral iron, like that's a problem. That's an, of course, because the hemodialysis patients have an IV so they get intravenous. Oral iron, if you've ever taken it, causes

cramps and constipation and gastric distress and a whole bunch of other things, but it's not worth starting an IV. So I didn't understand why that was in there.

MS. RAY: Because right now -- I didn't raise it as being a problem. I raised that as being for -- providers right now are paid for the injectable iron, but when a patient takes oral iron they're not. So the bundle of services that you're going to need for the hemo may be different than for the PD.

DR. ROWE: I see. This committee that you mentioned that MedPAC is on, would you remind us what that committeeis, and are you the MedPAC representative, or is there somebody else from MedPAC? It sounded like the whole MedPAC team was a representative.

MS. RAY: No, I'm the representative.

DR. ROWE: What is that?

MS. RAY: The University of Michigan is CMS's contractor for both phase I -- that helped them, that helped the Secretary write this current report, as well as phase II as the Secretary drills down to how they're going to modernize the payment system. So they have created an advisory board. This advisory board will meet twice during the upcoming year to advise the contractor on issues related to modernizing the system.

The best I can recall some of the other folks who have been asked to participate on the advisory board, and I can follow up with you in an e-mail, are some of the major dialysis providers.

DR. ROWE: I'm just wondering about our role. It's often unclear to me what MedPAC's role is vis-a-vis CMS. In other words, how cooperative, how much oversight there is, how much independent analysis in their report to Congress, et cetera. Should we be on CMS committees, or not? This is purely a procedural question. This happens to be dialysis. It's just that if CMS is either by themselves creating an advisory committee or through a vendor or a contractor or whatever and we're here commenting to the Secretary or Vice President or whoever about what CMS is doing, giving comments about the Secretary's report and everything, is it appropriate for us to be sitting on those oversight groups?

MR. HACKBARTH: My off-the-cuff reaction, Jack, is that in general I would welcome the opportunity to participate, and gain information from that, and provide expertise to the extent that we have it, with the important proviso that if, in this case Nancy is participating, she cannot commit the commissioners of MedPAC and say, this has been blessed by MedPAC and now we can't as commissioners disagree with it. She is participating as a staff person as opposed to as the embodiment of the Commission. So I don't think that we are foregoing our independence in any sense.

DR. ROWE: That is actually precisely -- I thought of that andf I agree with that and I think that's great. That's precisely why I reacted to the fact that she said that MedPAC was represented on the committee as opposed to her. I have a lot of respect for Nancy and her capacities

and singularity of her abilities here, but I don't think we should be thinking of it as if MedPAC is represented. I don't really care. If it's okay with you, it's great with me. I just thought I'd raise the question.

DR. REISCHAUER: I am about to disagree with you because I think Jack raised a very important issue. I don't know exactly what the structure of this is. Is it the University of Michigan asking you to be on it, or whether it's CMS asking you to be on it. I'm not sure what the University of Michigan is doing, whether it's providing input to the Secretary who is then going to do something, or it's providing the thing.

But to the extent it was providing the thing, then we get the thing and are asked to comment on. The fact that Nancy has been a party to this is, in a sense, co-opting this unless Jack and Glenn are going to write the draft of the comments of MedPAC on the new reg. I would welcome that; be more interested in it, but it is a problem.

DR. MILLER: I wouldn't say anything different, just perhaps different words. I think that there's lots of these things that go on often where people ask, we're going to put something together. We would like technical assistance. I have pushed also to try and always be connected to the outside environment so that when we walk into here and we get questions and people say, what are other people thinking or doing, we're able to do that.

I think all of this turns on the structure of the entity that we're asked to participate in. So if it's in this instance, the University of Michigan asking Nancy for technical assistance, you're right, we should be careful about the use of the words. I think the only thing that we have to be careful about is to assure that we're independent, and if structure doesn't look like it allows that, then we step out. I think it's really just looking at each of the instances.

I really would hate to have a blanket policy of we don't do this. I think that would be a real loss of information for us.

MR. HACKBARTH: One of the things that I had asked Mark to do when he became executive director was redouble our efforts to be plugged into what's happening with CMS and other parts of the government, become more involved. Not build walls around ourselves in the name of independence. I think in this case we can have our cake and eat it too, and participate and learn and provide help without compromising the independence of the Commission.

DR. NEWHOUSE: I guess I should, following on this last discussion, raise this with commissioners. I was a reviewer of the ARC report we're discussing tomorrow. I've been on CMS committees to review stuff. I've always assumed I was acting as an individual and that there wasn't an issue, but I should, I guess, raise that because there may well be other people in that situation.

However, the point I wanted to raise was actually a minor point. In a footnote, Nancy, you talk about that there's a potential bias toward in-center care because they

can bill for all drugs but the home patients can only bill for Epo. My question there was, is this a material bias? What proportion of dollars on drugs go to Epo?

MS. RAY: On a per-patient basis, I don't have --

DR. NEWHOUSE: It may be different for in-center and injectable. I'm looking for a ballpark. Is Epo 90 percent of it, or is it half of it, or what?

Before you send the comment letter, maybe we should find out if this is an important bias or not.

MS. RAY: With the $2.3 billion number, Epo is roughly $1.4 billion of that.

DR. NEWHOUSE: Then I might move it out of a footnote.

MS. RAY: Right. But just the issue that's going through my head is that for the subcutaneous, on average the dose is lower than on the IV. But notwithstanding that, yes, Epo is...

MS. DePARLE: I'm just interested, Nancy, in whether you have a reaction to the statement that Dr. Hakim, the nephrologist, made during the public comment period about the lack of pre-ESRD care. I think he used a statistic about most dialysis patients hadn't seen a nephrologist almost until right before they went on dialysis, which was troubling to me.

MS. RAY: Right. Again that's an issue that we'd like to drill down upon when we lok at the disease management. Getting folks with chronic kidney disease into physician care earlier in the process, not a month or two or three months before dialysis onset but a year. There is the potential -- there's some evidence out there in the peer review literature that it may improve their outcomes. We'd like to look at that evidence a little bit more closely, look at how they're measuring it.

But when a patient shows up one month prior to dialysis, the vascular surgeon is not going to be able to put in an AV fistula because it doesn't have a chance to mature. They're going to have to use another type of vascular access. The AV fistula is associated with fewer complications, so that is an issue that we will be looking at more closely.

DR. MILLER: Can I just follow up on that? Does the Medicare secondary care private handoff have anything to do with this or is that a question we would look at? Or is that just not relevant to this conversation? In other words, does somebody not show up with -- shows up at dialysis without seeing a nephrologist in part because they were handled through a different insurer before they got handed off to Medicare?

MS. RAY: I've never seen any evidence to that effect. I've never seen any of these studies looking at whether or not the patient is MSP or not when they're looking at the pre-ESRD care. That's something that we can look more closely at the studies to see if they've looked at it.

DR. NELSON: Nancy, we talk about what's included in the payment bundle and allude to our responsibility with

respect to the 2005 rate, but the other issue, whether the unit of payment should be a week or a month rather than a single episode we refer to in passing in the letter to the Secretary but we don't indicate in our workplan whether it would be useful for us to make a recommendation with respect to that. So I have two questions.

Number one, how do you feel about that? The second is, what do you hear from the provider community with respect to that issue, how they feel about it?

MS. MILGATE: In our March 2001 report we did recommend that CMS reevaluate the unit of payment to see if a weekly payment or even a monthly payment would make more sense. As you know, nephrologists are paid on a monthly capitated payment. The fact that dialysis is ongoing, three times a week every week, would point you in the direction of a longer unit of payment, either on a weekly basis they way peritoneal dialysis or more frequent hemodialysis is provided, or on a monthly basis.

DR. NELSON: So in the past, I understand that we said, this should be considered. Is it important enough for us to, and are there data that would allow us to make a recommendation with respect to a week or a month, not just say that this is something that ought to be considered?

MS. RAY: I think that's an issue that we could look into in the future in greater depth. I think one of the things, I guess to start out looking at that issue is to drill down a little bit more closely as to the other services being provided, and also getting a sense of how the provider community would feel about that change. Yes, we can certainly include that in our workplan as a future issue.

MS. BURKE: Nancy, I just had a question tracking from the letter to the workplan around the issues of quality. In the letter you note, I think correctly so, that we need to look at what additional or new measures need to be employed in order to determine the quality of services that are being provided and raise some questions about how we might do that.

In our workplan you talk about monitoring the trends in the quality of care by looking at the current performance measurement project. Do you anticipate that that project will in fact look at not only the adequacy of the current measurements but also what other indicators are likely to be appropriate? Because it would seem to me one of the questions, again to the point of how does one measure whether in fact care is being given appropriately if you begin to bundle in a larger bundle, whether there are things beyond the ones we know of today, whether it's nutritional status or albumin levels or whatever it happens to be, do you anticipate finding other indicators? Is that in fact part of what that project is likely to do, or that we are likely to seek from that project?

MS. RAY: The agency updated its measures back in 2000 and that's when they added measures looking at vascular access monitoring, for example. I would need to check back with the folks at CMS to see if they're thinking of adding

anything else right now. I do know that for the demo there are five quality indicators. One is on vitamin D supplements, and they're going to have to develop a measure based on that.

Now we as a commission can start looking at other potential measures that the agency can use.

MS. BURKE: [off microphone] But I think that, again, as part of the broader quality commitment that we're making, the question of what indicators are appropriate and how broadly are in terms of the mixture of things that you receive, again going back to our earlier conversation about the need for -- whether here as well there are measurements that we ought to think about that are not necessarily specific or narrowly defined but might impact on the essential quality of life. So we may want to think about that.

MR. FEEZOR: Nancy, in any of the valuative criteria, are there any routine surveys of the patients themselves in terms of their experience and satisfaction?

MS. RAY: Done by CMS, no.

MR. FEEZOR: Or by any reliable source.

MS. RAY: I don't know the extent to which the individual provider chains do that. I can follow up with them on that. CMS does not look at patient satisfaction.

MR. FEEZOR: In keeping with our patient-concentric, it would nice to point that out as something that...

MR. HACKBARTH: Shall we turn to the draft recommendation? Do people understand this or would they like a brief recap of the issue here?

MS. DePARLE: I think I understand the issue but I'm not sure of the context of the recommendation. Is the recommendation going to go in the letter?

MR. HACKBARTH: Yes.

MS. DePARLE: Is that the only thing we're making a recommendation on?

MS. RAY: Yes.

MS. DePARLE: Because it seemed like there were a number of things in the letter that we were commenting on, so it seems odd to just have one recommendation.

DR. MILLER: Isn't some of the nature of the things that we're commenting on is, we think the Secretary needs to pay attention to this, and as the Secretary's going through and developing the next generation, if you will -- I may be using that term a little out of line here. But here, based on work that we've done previously and so forth, we feel fairly clear that the Secretary should have the authority to do ahead and do this? Is that the distinction here?

MS. RAY: Right.

MR. HACKBARTH: Okay. Any other questions or comments about this? Any discussion?

All opposed to the draft recommendation?

All in favor?

Abstain?

Okay. Thank you.